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August 18, 2000

Mr. Joseph A. Levitt  
Director  
Center for Food Safety and Applied Nutrition  
200 C Street, S.W.  
Washington, DC 20204

Dear Joe:

Thank you once again for the opportunity to meet with you a few weeks ago. The Food Allergy Network (FAN) and the members of the American Academy of Allergy, Asthma and Immunology applaud the FDA's efforts in making the U.S. labeling regulations the best in the world. Our objective is to bring about improvements to these regulations that will improve the quality of life for the 6 to 7 million Americans who are affected by food allergies.

As I mentioned during our meeting, we would like to see food allergy labeling added to the FDA's "A list" of priorities with action items for this next year. To that end, per your suggestion, I would like to submit FAN's suggestions for food labeling improvements in priority order.

1. **Problem: Ingredient statements are written for scientists, not consumers.**

Food-allergic consumers must read every ingredient label every time they shop to determine whether or not a particular food is safe for them to eat. However, they often don't understand what they are reading. For example, milk is described in more than 15 different terms on a label, including casein, whey, curds, magnesium caseinate, and rennet casein, to name a few. Eggs can be listed a number of ways, including albumin or ovalbumin. Wheat can be listed a number of ways included as flour, semolina, durum, or farina. Other common allergy causing foods have similarly confusing synonyms.

When a doctor makes a diagnosis of food allergy, the doctor usually says to simply avoid milk, or eggs, etc. The learning curve for the parent or patient is steep when they begin to read ingredient labels and find that few products actually use common names such as milk or eggs. For the patient with multiple food allergies, it can be overwhelming and very frustrating to try to learn all the "surprise" ingredient terms for common foods.

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**Solution: Use simple English terms.** If the product contains milk, or eggs, or wheat, it should use these terms on the label. Ingredient statements should be simple enough for a 7-year-old to read and understand. Adults outside the patient's family, such as scout leaders, teachers, and childcare providers, read labels on behalf of food-allergic children. These individuals are not as well informed about the variety of synonyms found on food labels for common allergy causing foods, therefore, labels should be clear and easy for everyone to understand.

2. **Problem: "Non-dairy" is misleading, as it can include dairy.** Products labeled as "non-dairy" often contain casein, a milk derivative. Each year, FAN receives calls from parents whose milk-allergic children have suffered an allergic reaction because the parent believed the non-dairy flag on the product indicated that the product was dairy-free.

**Solution: Avoid confusing terms such as non-dairy.** If the product contains milk or milk byproducts, it should be listed as milk and the product should not be allowed to be advertised as "non-dairy".

3. **Problem: Major allergens are often "hidden" in terms such as Natural or Artificial Flavors.** Although present at low levels, there have been a number of allergic reactions in children from major allergens, such as milk, present in Natural Flavors. Further, when a parent or patient sees terms such as Natural or Artificial Flavors, they must call the manufacturer to determine whether the product contains one of the major allergens before they purchase that product. While some manufacturers willingly provide that information, too many tell the consumer not to buy any of their products or simply refuse to provide any assistance. If the individual is unsure whether the flavoring contains the allergen, they must avoid eating that food.

**Solution: Clearly label all major allergens when present at potentially hazardous levels.** A simple approach for flavors would be Natural ALLERGEN NAME Flavoring or Natural Flavors (Contains ALLERGEN), or a Contains ALLERGEN statement at the beginning or end of the ingredient declaration.

4. **Problem:** The use of precautionary allergen labeling is growing, further limiting the food choices of food-allergic consumers. While some companies are doing a very good job of carefully assessing the use of these statements, we are concerned that other companies are not as careful. The misuse of these terms is undermining the integrity of food labels. Some food-allergic consumers are ignoring

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the warning statements, seeing them simply as a company's approach to covering their legal liability. An example of an extreme use of precautionary allergen labeling is enclosed.

**Solution:** Develop a mechanism for enforcement of the guidelines set out in the 1996 FDA letter to the industry addressing the use of precautionary labeling.

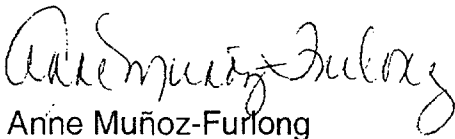
We have discussed these four food labeling improvements with industry groups, including the Grocery Manufacturers of America, the National Food Processors Association, and the Allergy Issues Alliance, which consists of major food-related trade associations. They are developing letters of support which should reach you soon.

In summary, food allergy is increasing as a major health concern. There is no cure. Food-allergic consumers must read all labels for all foods each time they shop — a tedious process that can take several hours.

Improvements in ingredient labels will enable patients to manage their food allergy more effectively and improve their quality of life. In addition to the medical risks associated with an allergic reaction, the problems and potential solutions we've identified will make life easier for the 6 to 7 million Americans affected by food allergies and for their family, friends, and other caregivers.

Please let me know if I can provide further information about food allergies from the consumer's perspective. Thank you for your time and attention to this matter.

Sincerely,



Anne Muñoz-Furlong  
Founder

cc: Ken Falci, Ph.D., FDA  
Christine Lewis, Ph.D., FDA  
Robert Wood, M.D., AAAAI and FAN Medical Advisor  
Steve Taylor, Ph.D., AAAAI and FAN Medical Advisor  
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## Background

- ◆ Food allergy is believed to affect 2 to 2 ½% of the American population or between 6 and 7 million people.
- ◆ Eight foods account for 90% of the allergic reactions: milk, eggs, peanuts, tree nuts, fish, shellfish, wheat, and soy.
- ◆ Up to 1.14% of the population or close to 3 million Americans are affected by peanut and tree nut allergy, according to "Prevalence of peanut and tree nut allergy in the US determined by a random digit dial telephone survey" published in the *Journal of Allergy & Clinical Immunology* in April 1999.
- ◆ Scientists estimate that food-allergic reactions account for up to 30,000 hospital visits a year. Food-allergic reactions are the leading cause of anaphylaxis outside the hospital setting, surpassing reactions to medications and insect stings combined.
- ◆ These reactions are believed to cause between 100 to 200 deaths annually. Peanuts, tree nuts, fish and shellfish are believed to be the leading cause of anaphylaxis in the US.
- ◆ There is no cure for food allergy. Strict dietary elimination of the allergy-causing food is the only way to avoid a reaction; as a result, food allergic individuals are totally dependent upon food ingredient information.
- ◆ Reading ingredient statements can be a long and burdensome process. Ingredients change frequently and vary with the size of the package. As a result, food-allergic individuals must read every ingredient statement for every product every time they go to the grocery store.
- ◆ Individuals with milk allergy are relying on Kosher labeling for a shortcut to allergy reading and it does not work.
- ◆ FAN recent surveyed attendees at 3 Patient Conferences (VA, IL, & NY) about food labeling concerns. Of 487 respondents, 90% were FAN members, 83% had children under 12, 30% were allergic to milk or eggs, 58% were

allergic to peanut or tree nut. When asked whether they had ever called food manufacturers for more information about a product's ingredients, 82.5% reported they had.

- ◆ There have been a number of allergic reactions reported due to unclear labeling.

## Problems

1. **Ingredient statements are written for scientists, not consumers.** Food-allergic consumers must read every ingredient label every time they shop to determine whether or not a particular food is safe for them to eat. However, they often don't understand what they are reading. For example, milk is described in more than 15 different terms on a label including casein, whey, curds, magnesium caseinate, and rennet casein, to name a few. Eggs can be listed a number of ways, including albumin or ovalbumin. Wheat can be listed a number of ways included as flour, semolina, durum, or farina to name a few.

When a doctor makes a diagnosis of food allergy, the doctor usually says to simply avoid milk, or eggs, etc. The learning curve for the parent or patient is steep when they begin to read ingredient labels and find that few products actually use common names such as milk or eggs. For the patient with multiple food allergies, it can be overwhelming and very frustrating to try to learn all the "surprise" ingredient terms for common foods.

2. **Major allergens are often "hidden" in terms such as Natural or Artificial Flavors.** Although present at low levels, there have been a number of allergic reactions to children from major allergens such as milk present in Natural Flavors. Further, when a parent or patient sees terms such as Natural or Artificial Flavors, they must call the manufacturer to determine whether the product contains one of the major allergens, before they purchase that product. While some manufacturers willingly provide that information, too many tell the consumer not to buy any of their products or simply refuse to provide any assistance. If the individual is unsure whether the flavoring contains the allergen, they must avoid eating that food.
3. **"Non dairy" is misleading, as it can include dairy.** Products labeled as "non dairy" often contain casein, a milk derivative. Each year FAN receives calls from parents whose milk-allergic children have suffered an allergic reaction because the parent believed the non-dairy flag on the product indicated that the product was dairy-free.
4. **The use of precautionary allergen labeling is growing, further limiting the food choices of food-allergic consumers.** While some companies are doing a very good job of using carefully assessing the use of these statements, we are concerned that other companies are not as careful. The

misuse of these terms is undermining the integrity of food labels. Some food-allergic consumers are ignoring the warning statements, seeing them simply as a company's approach to covering their legal liability. An example of an extreme use of precautionary allergen labeling is enclosed.

### **Potential Solutions**

1. **Add food allergy labeling improvements to the FDA Priority A list with action steps.**
2. **Require food labels to declare the presence of commonly allergenic foods**, consistent with the recently adopted recommendations of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) Codex Alimentarius.
3. **Use simple English terms.** If the product contains milk, or eggs, or wheat, it should use these terms. Keep in mind that many of the patients who are food-allergic are young children. Therefore, ingredient statements should be simple enough for a 7 year-old to read and understand. Other adults, such as scout leaders, teachers, and childcare providers, read labels on behalf of food-allergic children. Labels must be clear and easy for everyone to understand.
4. **Avoid confusing terms such as non-dairy.** If the product contains milk or milk byproducts, it should be listed as milk and the product should not be allowed to be advertised as "non dairy".
5. **Clearly label all major allergens when present at potentially hazardous levels.** A simple approach for flavors would be Natural ALLERGEN NAME Flavoring or Natural Flavors (Contains ALLERGEN), or a Contains ALLERGEN statement at the end of the ingredient declaration.
6. **Develop a mechanism for enforcement of the guidelines set out in the 1992 FDA letter to the industry addressing the use of precautionary labeling.**

### **Summary**

Food allergy is increasing as a major health concern. In addition to the medical risks associated with an allergic reaction, the problems and potential solutions we've identified will make life easier for the 6 to 7 million people affected by food allergies. Improvements in ingredient labels will enable patients to manage their food allergy more effectively and improve their quality of life.

We applaud the FDA's efforts in making the US labeling regulations the best in the world. Our objective is to bring about improvements to these regulations that will improve the quality of life for individuals with food allergies.

## Product-Related Member Calls

Sun Soy - Julie Stolte (508-234-8628) called to report her son's anaphylactic reaction to this soy milk, distributed by Morningstar Foods. They usually use Silk soy milk, but the store was out of it, so they bought this brand for the first time. The 21-month-old milk-allergic boy drank 8 ounces of Sun Soy and immediately started vomiting repeatedly. He sneezed 50 or more times, started breaking out in hives, and his eyes started to swell. They put him in the car and started driving to the hospital. Halfway there he was getting worse, so they pulled in to a police station and used the EpiPen and he started improving immediately. An ambulance was called, and he was transported the rest of the way by ambulance, a 10-12 minute drive. When he arrived at the ER his hives began spreading from head to toe. His lungs were not involved. He was treated with IV Benadryl and steroids. The doctor called the manufacturer at 1-800-441-3321 - they said there are no milk ingredients in the product, and that the line is thoroughly cleaned after it processes a milk product and there's no way any of the milk product could be in the Sun Soy. The allergist had one of the parents go to the supermarket to get their usual brand of soy milk to give to the child while he was still at the hospital to be sure he had not developed an allergy to soy. He drank it without a problem. They still have the remainder of the opened container of Sun Soy and will report the reaction to the FDA.

7/26/00

Mrs. Butterworth's Original Syrup - Aleesha Christopher (Marietta, GA) reported that her milk-allergic son has safely eaten Mrs. Butterworth's Lite Syrup before. She gave him Mrs. Butterworth's Original Syrup. He had a mild reaction. The label did not list milk ingredients. She called Mrs. Butterworth's (Aurora Foods) and was told that the flavorings contained milk.

7/26/00

Marino's Italian Ices - Lori Carlino (631-751-6613) called to let us know she bought this product, but when she opened it she found that the ingredients printed on the top of the lid do not match the ingredient list on the outside of the package. When she called the manufacturer at 718-849-6200 they told her they are in the process of repackaging and that they don't know where the problem is. However, they did tell her the product contains no milk ingredients.

7/14/00

Mrs. Baird's Honey 'n Wheat Bread - I received this e-mail from Kristene Augusta" I have been buying Mrs. Baird's Honey 'n Wheat bread for the last few months. I bought it because it was milk and egg free. Then, last week I bought a loaf that had milk listed as an ingredient. I called the company and the woman told me that she thought it DID have milk. Today I recieved a letter from the company stating that "The ingredient legend should include nonfat milk. We apologize for the misprint on the package. We are in the process of revising the package nutritional information." It is signed by Don Perkins, General Manager. His phone number is 915.692.3141. When at the store Saturday, there were still loaves on the shelf without milk listed.

5/5/00



Duncan Hines Vanilla Icing - Janet Leydorf (410-672-5789) called to tell us her milk-allergic son had a reaction. After eating a small quantity he had itching on his forearms and little hives. After 40-45 minutes, he complained that his throat felt funny, but he may have been coming down with a cold. Janet did not put him to bed, but gave him Benadryl and watched him for 4 hours. She gave him more Benadryl, and the reaction never got serious. When she called Duncan Hines she was told that the vanilla icing has dairy in the natural and artificial flavors.

12/23/99

Snack Ramen Noodles, Oriental Flavor - Mary Graham (850-932-0838) called Mary Jo and said her 8-year-old milk-allergic son had a reaction to Lot #11230026. When she called Union Foods Inc. at 714-734-2200, she was told that the product contains whey, which is not listed on the label. They seemed unconcerned about her son's reaction. She was planning to call the FDA's Consumer Complaint Coordinator.

12/23/99

White Wave Silk Nog - Karen Doty (708-848-2932) bought this product, which is made from soy milk. No egg ingredients were listed, but before using it she called to be sure it would be safe for her egg-allergic child. She was told that the natural flavoring not only contains egg, but also nuts and milk.

11/12/99

Rice Dream Vanilla Frozen Dessert - Susan McDonald (425-868-1385) called to tell us her milk-allergic son had a reaction to this product while they were on vacation in early July. They were staying at her mother's house and were very careful, as always, about using clean utensils, etc. He reacted immediately, needed EpiPen and a trip to the emergency room. They reported the reaction to Imagine Foods; got a letter back from Mary Stiff in Consumer Relations saying there was no possible way the product could have been cross-contaminated with milk, that the code number indicates their package was more than 5000 units into the run.

8/13/99

Jolly Time Microwave Popcorn, Crispy White and Crispy White Lite - Amy Webb (208-524-2752) called the manufacturer about the flavoring in a Jolly Time popcorn she had. She was told the kind she had didn't have any peanut or nut ingredients, but that the flavors above do contain nut or peanut in the flavoring. She asked if it was labeled on the package and they told her no, it just says natural flavoring. They told her all flavors are run on the same equipment, which is washed in-between. Jolly Time's phone number is 712-239-1232, she thinks she spoke to Scott, but didn't write down the name.

7/2/99

Balance Nutrition Bar - Noreen Heavlin (650-712-1633) called to tell us her peanut-allergic son had a serious reaction when he ate the cranberry flavor. He had eaten the cranberry bars at least 10 times before without a problem. This time his throat was swelling very quickly - so badly that he was not able to swallow Benadryl. They used the EpiPen and got him to the hospital. Phil LeClair (1-800-678-4246, extension 2214) told her that they make a peanut butter bar and that in 6 months their other flavors will have a peanut warning on the label, but they're going to use up current stock.

4/9/99





Rice Dream Nutty Bar - a member called because her milk-allergic child had a reaction. She had called Imagine Foods, who told her there are no milk ingredients, but it is run on a line with milk products, and there could be some milk in the product that the FDA does not require that they list on the label. She was going to call the FDA.

3/26/99

Healthy Choice Microwave Popcorn-Natural - Carrie Norton (410-337-5082) called because her son broke out in hives. She learned that there are egg and peanut ingredients in the natural flavorings. She's going to fax us a copy of the letter they sent her.

3/5/99

Quaker Strawberry Crunch Corn Cakes - Beth Whitley called to say that she was told by Quaker (1-800-856-5781) that there is dairy in the natural flavoring.

1/29/99

Brach's Candy Corn - Dawn Torres (203-245-0351) called because her 2 peanut-allergic daughters both had mild reactions after eating candy corn and pumpkins. Both had hives and one had a tingling in her mouth. When Dawn called Brach's they were not concerned. She's going to call the FDA.

11/30/98

Snackwell's Chocolate Mint Cookies - Ellen Giblin's daughter had a reaction. When they read the ingredients (later) they saw that peanut flour is the last ingredient on the list. She called Nabisco at 800-622-4726 and they told her peanut flour is not really an ingredient, but they are run on shared equipment with peanut products and because they had a lot of people calling about reactions they've decided to put peanut flour on all their packages when they are reprinted.

11/23/98

